REMARKS/ARGUMENTS

The Office has required restriction in the present application as follows:

Group I: Claims 46-107, drawn to liquid pharmaceutical composition comprising follicle stimulating hormone and a variant thereof.

Group II: Claims 108-159, 165-170 drawn to a freeze-dried composition and a kit comprising follicle stimulating hormone and a variant thereof.

Group III: Claims 160-164, drawn to a method for manufacturing a pharmaceutical composition comprising follicle stimulating hormone and a liquid diluent.

Group IV: Claims 171-176, drawn to a method for manufacturing the freeze-dried formulation comprising follicle stimulating hormone and subjecting the mixture to lyphilisation.

Group V: Claims 177-182, drawn to a method for treating infertility comprising a liquid pharmaceutical composition comprising follicle stimulating hormone and a variant thereof.

Group VI: Claims 183-188, drawn to method for treating infertility comprising a freeze-dried composition further comprising follicle stimulating hormone.

In addition, the Examiner has indicated that the claims are directed to more than one species of the generic invention and that the species lack unity of invention and the Examiner is also requiring election of a single species chosen from: follicle stimulating hormone, luteinising hormone, and combinations thereof.

Applicants elect, with traverse, Group I, Claims 46-107. With respect to the non-elected process claims identified in the groups above, Applicants request rejoinder of these method claims upon finding the elected claims allowable (see MPEP 821.04).

Further, Applicants elect, with traverse, FSH for initial examination purposes. Claims 46-89 are believed to read on the elected species.

The Examiner, citing PCT Rule 13.1 and 13.2, contends that the above Groups do not relate to a single general inventive concept because they lack the same or corresponding special technical features. Specifically, the Office argues that the application lacks unity of invention under PCT Rule 13.1 because, under PCT Rule 13.2, the shared

technical features is rendered obvious by Backstrom et al (USPN 6, 524,557) and Cleland et al (USPN 6,113,947).

The Applicants respectfully traverse the Restriction Requirement on the ground that unity of invention does exist between Groups I-X because there is a technical relationship that involves the same special technical feature. It is this technical feature that defines the contribution which each of the Groups, taken as a whole, makes over the prior art.

In particular, as specified in the claims the invention arises from the combination of specific surfactants a gonadotropin (e.g., FSH, LH, and their variants). US '557 describes aerosol formulations with a polypeptide and surfactant. The surfactants describes in US '557 can be specific fatty acids or salts, a bile salt, a phospholipids or an alkyl saccharide. The polypeptides can be chosen from a long list bridging two columns (2-3). While FSH is mentioned, the preferred polypeptide is clearly insulin (see col. 3, line 14 and all of the Examples). No pluronic surfactants are described. US '974 describes microencapsulations with controlled release and includes Nerve Growth Factor (NGF) with a metal, such as zinc, in a biopolymer encapsulated form. US '974 also describes a generic listing of optional components including emulsifiers, antifloculants, stabilizers, bulking agents, buffer agents, chelating agents, antioxidants, cosolvents , a non-ionic surfactants such as pluronic F68 (see col. 12, 13, 14, 18 and 23-24). US '974 does not describe or suggest using any other polypeptide but NGF and certainly not FSH or LH.

The Office's rationale for alleging that the claims would have been obvious lacks support. Moreover, in fact, one would not have any reason to combine a US ''557, teaching aerosolized insulin, and US '974, relating to controlled release of NGF. Clearly, hindsight reconstruction of the claims has been done here, which is improper.

Applicants further traverse the Restriction Requirement on the ground that the Office has

Moreover, the MPEP in §803 states as follows:

If the search and examination of an entire application can be made

without a serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Applicants respectfully submit that a search of all the claims would not impose a serious burden on the Office.

The Election Requirement is respectfully traversed for at least the same reasons as discussed above. Therefore, the Election of Species Requirement is improper and should be withdrawn.

Finally, with respect to the elected species, Applicants respectfully submit that, should the elected species be found allowable, the Office should expand its search to the non-elected species.

Accordingly, and for the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the Restriction and Election of Species Requirement. Withdrawal of the Restriction and Election of Species Requirement is respectfully requested.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice of such action is earnestly solicited.

Respectfully submitted,

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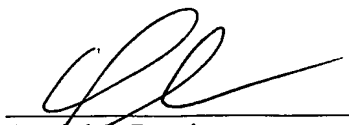

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